510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k061838

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator for Calcium (CA), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Magnesium (MG), Thyroxine (T4), Thyronine Uptake (TU), Blood Urea Nitrogen (BUN) and Uric Acid (URCA).

D. Type of Test:

Not Applicable

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista Chemistry 1Calibrator, (KC110)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
Calibrator, Multi-Analyte Mixture (JIX)	Class II	21 CFR 862.1150, Calibrator.	75 Clinical Chemistry (CH)

H. Intended Use:

1. Intended use(s):

   See indications(s) for use below.

2. Indication(s) for use:

   The CHEM 1 CAL is an *in vitro* diagnostic product for the calibration of Calcium (CA), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Magnesium (MG), Thyroxine (T4), Thyronine Uptake (TU), Blood Urea Nitrogen (BUN) and Uric Acid (URCA) methods on the Dimension Vista™ System.

3. Special conditions for use statement(s):

   For prescription use

4. Special instrument requirements:

   Dimension Vista™ System

I. Device Description:

CHEM 1 CAL is a liquid, multi-analyte, bovine serum albumin based product containing calcium, cholesterol, creatinine, glucose, lactic acid, magnesium, thyroxine, urea nitrogen and uric acid. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 2.5 mL.

J. Substantial Equivalence Information:

	Device	**Predicate Devices**				
Item	**Dimension Vista™ System Chemistry 1 Calibrator2**	**CHEM I Calibrator k860021 (URCA–k862359)**	**Chemistry II Calibrator k861700**	**Cholesterol Calibrator k861700**	**Thyroxine Calibrator k862359**	**Thyronine Uptake Calibrator k862359**
Form	Liquid.	Lyophilized.	Liquid.	Lyophilized.	Lyophilized.	Lyophilized.
Traceability	**BUN – NIST SRM 9122 CA – NIST SRM 915.** CHOL – Abell-Kendall	BUN – NIST SRM 912 CA - NIST SRM 915.	MG - NIST SRM 929A	CHOL – NIST SRM 911.	T4 – Thyroxine Master Pool.	TU – Thyronine Uptake Master Pool.

	Device	Predicate Devices				
	(CDC-NCEP). CREA – NIST SRM 914. GLU – NIST SRM 917. LA – Lactic acid – lithium salt A-Grade. MG – NIST SRM 929A. T4 – USP. TU – Calculated value. URCA – NIST SRM 913.	CREA - NIST SRM 914. GLU - NIST SRM 917. LA - Lactic acid – lithium salt A-Grade. URCA - NIST SRM 913.				
Matrix	Bovine serum albumin based product.	Bovine serum albumin based product.	Pure magnesium dissolved in a dilute Solution of HCL, reagent grade potassium dihydrogen phosphate and reagent grade glycerol.	Bovine serum albumin based product.	Human serum based product.	Human serum based product.
Number of Levels	Two levels.	Three levels.	Three levels.	Three levels.	Five levels.	Five levels.

K. Standard/Guidance Document Referenced (if applicable):

STANDARDS
Title and Reference Number
Stability Testing of In Vitro Diagnostic Reagents (13640)
Medical devices - Application of risk management to medical devices (14971:2000)

GUIDANCE			
Document Title	**Office**	**Division**	**Web Page**
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	**OIVD**		**http://www.fda.gov/cdrh/ode/calibrator.html**
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use			**http://www.fda.gov/cdrh/ocd/guidance/4444.html**

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable

b. Linearity/assay reportable range:

Not Applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability: The assigned values of the Chemistry 1 Calibrator were verified on a Dimension® Vista™ System calibrated with an approved Master Pool. Master Pool values were assigned on multiple Dimension® clinical chemistry instruments. According to the sponsor the traceability of the assigned values of the Chemistry 1 Calibrator was standardized to the below table of assigned values.

Constituent	Traceability
BUN	NIST SRM[a] 912
AC	NIST SRM 915
CHOL	NIST SRM 911 (CDC[b]) Abell-Kendall reference method
CREA	NIST SRM 914
GLU	NIST SRM 917
LA	Lactic Acid Lactic acid- lithium salt (A- Grade)
MG	NIST SRM 929A
T4	USP[b]

TU	Calculated value
URCA	NIST SRM 913

[1] National Institute of Standards and Technology – Standard Reference Material.
[b] CDC: Centers for Disease Control
[c] United States Pharmacopeia.

Stability: The target shelf life for the Dimension Vista® Chemistry 1 Calibrator is 12 months. A vial punctured by the instrument and stored on board has a stability claim of one day. An open vial not stored on the instrument, but recapped and stored in a refrigerator has a stability claim of 30 days. Stability study protocols and acceptance criteria were described and found to be acceptable.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.